

REMARKS

By way of summary, Claims 1-28 are pending in this application and are presented herein for consideration. New Claims 29-32 have been added. No claims have been canceled or amended. Claims 1-32 are pending for consideration.

§ 103(a) Claim Rejections

Claims 1-28 have all been rejected as obvious the combination of at least U.S. Patent No. 6,530,926 to Davison and U.S. Patent No. 6,485,518 to Cornwall et al. Applicant traverses these rejections as discussed below.

1. Claims 1-4, 6-12, 14-18, and 23-28 are not obvious in view of Davison and Cornwall

Applicant traverses the rejection of Claims 1-4, 6-12, 14-18, and 23-28 as obvious in view of Davison and Cornwall.

The Examiner must establish a prima facie case of obviousness. M.P.E.P. § 2142. To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

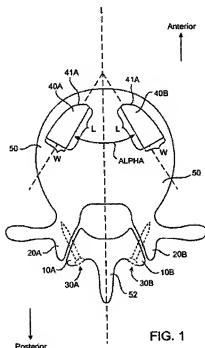
Also, the prior art must suggest the desirability of the claimed invention to establish a suggestion or motivation to modify the references. M.P.E.P. § 2143.01 [I]. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006). Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another. *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir.

1991). M.P.E.P. § 2143.01 [II]. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). M.P.E.P. § 2143.01 [III]. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). M.P.E.P. § 2143.01 [V].

As discussed in greater detail below, the Examiner has failed to establish a proper combination or a prima facie case of obviousness of the pending claims.

Cornwall

Cornwall discusses a technique for precisely locating narrow implants, i.e., bone allografts 40A, 40B and facet screws 30A, 30B. More particularly, Cornwall discusses delivering these narrow implants through narrow cannulae to ensure that the allografts and screws are in a specific triangle orientation illustrated in Figure 1.



Cornwall emphasizes that the implants should be precisely positioned to provide intervertebral support at “three locations in particular, with these three locations together forming a triangle.” Col. 1, ln. 67 to col. 2, ln. 1. Cornwall touts the advantage of triangular positioning,

stating that "the present three point (i.e.: triangular) support system is that support is provided in three perpendicular directions, (thereby providing support with respect to forward-backward bending, side-to-side bending and torsion of the spine)." Col. 2, ll. 7-11. This arrangement provides "enhanced stability," according to Cornwall. Col. 2, ll. 14-15.

Cornwall also teaches that the implants 40A, 40B should be positioned at specific angular positions relative to each other. The angle ALPHA, illustrated in Figure 1, provides support along axes that are angled relative to each other (see the dashed lines). Since the present pair of bone allografts are positioned at an angle to one another, tall, narrow bone allografts can be used. The narrow implants facilitate insertion through a narrower cannulated passageway.

Cornwall teaches using specifically-oriented narrow cannulae coupled with an external surgical guide-framing system to precisely deliver the implants locations. The guideframes are illustrated in Figures 3 and 4.

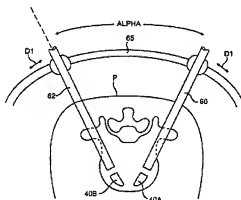


FIG. 3

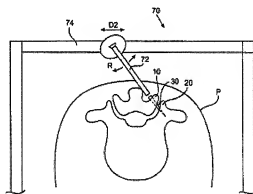


FIG. 4

The straight cannulae 60, 62 enable the bone allografts to be inserted into the patient's intervertebral space "in a relatively straight path through the cannula(e) and into the patient's intervertebral space." Col. 2, ll. 58-59. Using this technique the screws, like the allografts can be precisely positioned, with the help of the guideframe structures to achieve the arrangement called for in Cornwall. See, e.g., Cornwall col. 4, ll. 44-46.

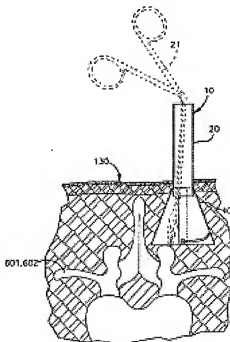
Cornwall also teaches away from disrupting tissue at Col. 1, ll. 35-40, where Cornwall states that a drawback of the installment of existing spinal support systems is that such

installation "typically also requires a large amount of tissue to first be removed from the patient's intervertebral space so as to make way for the device." Cornwall col. 1, ll. 37-40.

Thus, Cornwall uses narrowly cannulae and slender implants to provide specific targeting of the implants and to minimize tissue disruption near the spine.

Davison

Davison discloses a method of fixing vertebrae of a patient together at a surgical site. In the Davison method, a cannula 10, which is a form of an elongate body capable of providing access to a patient's spine, is inserted into the body of the patent. A first fastener is moved through the cannula 10 and is secured to a first vertebra. A second fastener is moved through the cannula 10 and is secured to a second vertebra. A first fixation element is moved through the cannula 10 and is fixed to the first and second fasteners. See, e.g., Davison, Abstract and Col. 1, ll. 35-44. Davison also discloses that the cannula 10 is enlargeable to an enlarged configuration that has an enlarged cross sectional area at the distal end for accessing a spine.



The enlarged cross sectional area provide by the enlarged cannula 10 increases access to the spine and also increases the degrees of freedom for inserting and positioning implants.

The Combination of Cornwall and Davison is Improper

The combination of Cornwall and Davison is improper because there is no suggestion or motivation to modify Davison or Cornwall as suggested in the Office Action and the combination would frustrate the purposes of and provide conflicting teachings.

There is no suggestion or motivation in the references to combine the Cornwall and Davison. Davison discloses a method of performing fixation where separate screws are advanced, in one embodiment, into separate vertebrae and a fixation member is coupled between the separate vertebrae. Though Cornwall discussed inserting a facet screw, there is no suggestion in Cornwall how such a technique can be used in connection with a fixation member. Also, Cornwall teaches the importance of narrow, slender cannulae to facilitate precise positioning of the facet screws. There is no suggestion in Cornwall of an expandable elongate body such as is taught in various embodiments of Davison. Rather, the slender nature of the Cornwall cannulae is critical to the proper placement of the Cornwall implants, as discussed above.

Furthermore, increasing the size of the Cornwall cannulae would reduce the precision with which the Cornwall implants can be placed. This would frustrate the purposes of the reference. The combination would frustrate the purpose of achieving the angularity and triangular arrangement of the Cornwall implants. As discussed above, Cornwall discloses the use of narrow cannulae to deliver implants to specific locations with the use of an external surgical guideframe as shown in Cornwall Figures 3 and 4. However, if an enlarged elongate body were used, as discussed in Davison, the increased workspace at the distal end thereof would defeat the purpose of Cornwall's specifically oriented guideframes that orient narrow cannulae to deliver narrow implants to specific locations at specific orientations. Thus, the combination of Davison and Cornwall would frustrate the purpose of Cornwall, rendering it unsatisfactory for its intended purpose, discussed above. See, e.g., *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). M.P.E.P. § 2143.01 [V]. For at least these reasons, Davison and Cornwall are not combinable.

Thus, for at least the reasons set forth above, the Examiner has therefore failed to establish a prima facie case of obviousness. Accordingly, Applicant traverses the rejection of Claims 1-4, 6-12, 14-18, and 23-28. Accordingly, Applicant requests that the rejection of Claims 1-4, 6-12, 14-18, and 23-28 be withdrawn.

2. Claims 5 and 13 are not obvious in view of Davison and Cornwall in further view of Neubardt

Applicant traverses the rejection of Claims 5 and 13 as obvious in view of Davison, Cornwall, and U.S. Patent No. 5,196,015 to Neubardt.

The shortcomings and non-combinability of Davison and Cornwall have been discussed above. The Examiner relies upon Neubardt as teaching "an indirect scoring of the area that is performed by placing the tool to the area and verifying the mark of the tool tip by indicia located on the tool shaft." Office Action, P. 3. Thus, there is no assertion in the Office Action that Neubardt has any teaching regarding providing access to the spine through an access device, which can be minimally invasive. Moreover, Applicant could not identify any teaching in Neubardt regarding such access. Accordingly, the combination of Davison, Cornwall, and Neubardt cannot overcome the deficiencies of the combination of Davison and Cornwall, discussed above. Accordingly, Applicant traverses the rejection of Claims 5 and 13 and requests that the rejection of these claims be withdrawn.

3. Claims 19-22 are not obvious in view of Davison and Cornwall

Applicant traverses the rejection of Claims 19-22 as obvious in view of Davison and Cornwall for the reasons set forth above. In particular, the combination of Davison and Cornwall is improper and for at least this reason, the Examiner has not established a prima facie case of obviousness. Accordingly, Applicant traverses the rejection of Claims 19-22 and requests that the rejection of these claims be withdrawn.

New Claims

Applicant has added new Claims 29-32 to claim additional aspects of Applicant's invention. Applicant respectfully submits that these claims are not taught or suggested by the cited art. Applicant respectfully requests the Examiner to allow new Claims 29-32.

CONCLUSION

Applicant respectfully submits that Claims 1-32 are in condition for allowance. Any remarks in support of patentability of one claim should not be imputed to any other claim, even if

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similar terminology is used, because patentability rests on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein.

Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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